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Social and Legal Development of Assisted Reproductive Technology in India

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ABSTRACT: *In many nations today, IVF and ART are common practises that are governed by legislation, rules, or ethical guidelines created by committees. These techniques have developed quickly, exposing some social difficulties that need to be addressed. Since deviations from this pattern (single mothers and lesbians) have access to these therapies, many people no longer view the standard heterosexual pair as the only "ivf appropriate patient". Age restrictions, selective embryo reduction, pre-implantation genetic diagnosis, surrogacy, and cloning are all viewed differently in different nations because societal, religious, and legal considerations have an impact on how these concepts are defined and used.This essay makes an effort to discuss both the socio-legal implications of reproductive technology and the infertile component of reproductive healthcare along with the legal development of the ART Bill from the inception of the non-binding guidelines to the formation of the Assisted Reproductive (Regulation) Bill, 2021.*

KEYWORDS: *Artificial insemination, ART, Surrogate mother, Embryo, Guidelines*

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I. INTRODUCTION

In both plants and animals, reproduction remains the core of life. Although sexual orientation and procreation remain the primary impulse of human beings, which sustains generational perpetuity and propagates societal security, not all is fair in love and fertility. The institution of marriage is the socio-legal manifestation of sexual behaviour among humans, and procreation, along with sexual enjoyment and religious functions, remains the primary goal of weddings. Marriage is the expression and commercialization of love, copulation, and reproduction. The birth of a child completes the nuptial relationship and enhances the conjugal bond between husband and wife. The child-parent bond is the bedrock of family, kinship, and society, and a child's intrinsic right to know his or her paternity and familial affiliation is a symbol of human dignity recognised by civilised countries.

Although sexual orientation and reproduction are biological processes, they are subject to tight socio-legal regulation under the auspices of Personal Laws influenced by numerous religions. Parentage is becoming increasingly personalised and separated from the province of 'lawful wedlock,' a subset of human rights that has gained global recognition. Live-in relationships, single parenthood, virgin birth, surrogacy, and LGBT reproductive rights in the age of in vitro fertilisation (IVF), among other things, are emerging modes of modernity in family affairs, and the traditional institution of marriage is forced to adapt. IVF has changed reproduction and made it easier to cross bodies (in terms of gametes and the womb) and borders (in terms of reproductive tourism and sperm/ova export/import).

Louise Brown, the first child born by in vitro fertilisation, was born on July 25, 1978 in Oldham, England. In 2010, Robert G Edwards received the Noble Prize. On January 14, 1992, Gianpiero D. Palermo devised the ICSI procedure, which resulted in the first successful birth. Since then, the number of children born through ART has increased dramatically, with over 8 million children globally as of 2018. Bauquis (2018) (ESHRE) According to research published by the Indian Council of Medical Research (ICMR), India has 1657 ART clinics, 385 of which have the necessary infrastructure and trained personnel and have registered, and the remaining 802 are not yet on the national registration. There is no reliable data on the number of children born in India as a result of ART. (Kalra 2016)

Parents are experimenting with donor-assisted conception and various forms of IVF not just to treat infertility, but also to facilitate other goals such as virgin birth, commercial surrogacy, gamete sales, and designer babies. In commercial terms, assisted reproduction has grown into a multibillion-dollar baby market. Overall, reproductive methods have impacted the equity between the rights of the parent/s and the kid in a tangential way, and the issues surrounding aided procreation demand a thorough examination.

II. REPRODUCTIVE RIGHTS AND INFERTILITY

Infertility is a common medical problem around the world that is viewed as a divine curse, resulting in a slew of socioeconomic and psychological hardships for bereft couples and individuals. Extramarital relationships, domestic violence, divorce, witchcraft, depression, suicide, and other societal stigmas, such as ostracism, can all result from sterility. As a result, infertile people become desperate for 'family building,' and are more likely to fall prey to so-called God men and local quacks. Since the dawn of time, mankind has sought answers to the topic of fertility, but it was not until the twentieth century that the medical profession began to address infertility as a disease.

Despite the fact that pregnancy and childbirth are basic biological processes, every civilization with cultural diversity has an inbuilt mechanism for managing them. In general, personal laws encourage procreation inside the confines of marriage, while third-party sexuality and impregnation are prohibited and punished. Father is supposed to be a socio-legal fiction under archaic family rules, and within 'lawful wedlock,' social and biological fathers are assumed to be one identity. Marriage is protected by the cocoon of legitimacy, but a child born outside of a valid marriage is labelled "illegitimate," resulting in a societal stigma and a slew of legally sanctioned discriminations. The existing socio-legal framework supports fatherhood's legitimacy, and 'parentage determination' is employed to enforce the notion of legitimacy in general. In the actual world, however, privacy in sexuality and procreation hides third-party intervention in procreation, and social paternity takes precedence over biological parentage in the socio-legal domain.

As a result, parenthood becomes a complicated issue, and knowing one's origins becomes increasingly important in social settings. Despite the fact that numerous International Conventions support for a child's right to know paternity, there are some constraints to tracing a child's genetic origin.

WHO defines*, "Reproductive rights rest on the recognition of thebasic right of all couples and individuals to decide freely and responsiblythe number, spacing and timing of their children and to have theinformation and means to do so, and the right to attain the higheststandard of sexual and reproductive health. They also include the rightof all to make decisions concerning reproduction free of discrimination,coercion and violence."*

Most people want children at some point in their lives, whether it's because of biology, emotional needs, or social pressures. Adoption was the main institution for validly mitigating the burden of infertility until assisted reproductive technologies (ARTs) came into existence. Adultery, a socially and legally sanctioned sexual act, was another covert strategy to avoid male infertility in marriage. Adoption and assisted reproduction (which includes adultery because males surreptitiously assist in impregnating women whose husbands may be sterile) fostered the separation of biological and socio-legal paternity.

Reproductive health care, sexual health, and reproductive rights became recognised under different International and Regional Human Rights Instruments in the late twentieth century. Reproductive rights have permitted sexual orientation and conception outside of antiquated marital and religious limitations, and were highlighted in the Tehran Declaration of 1968. The 1994 International Conference on Population and Development underlined the multiplicity of civil, political, economic, social, and cultural rights influencing individuals' and couples' sexual and reproductive lives. Although adoption is still a societal tool for finding a legal successor, the stigma of infertility continues to hound infertile couples and people.

III. ASSISETD REPRODUCTIVE TECHNOLOGY (ART)

Assisted Reproduction Technologies (ARTs) were introduced as a wonder of reproductive science in 1978, when test-tube baby Louise Joy Brown was born, escalating the dreams of millions of infertile couples of having their own children through third-party assistance in reproduction. The most common types of ARTs include gestational carriers (surrogates), in vitro fertilisation (IVF), gamete intra-fallopian transfer (GIFT), zygote intra-fallopian transfer (ZIFT), embryo cryopreservation, and egg or sperm donation.

ARTs evolved into a scientific tool for experimenting with and manipulating conception, and the trajectory of reproductive rights accelerated. In vitro fertilisation (IVF), a rapidly growing global industry, is the most common type of ART, in which sperm and ova are fertilised in the laboratory and the resulting embryo (zygote) is implanted in the womb regardless of the mother who contributes the ovum. IVF has commoditized pregnancy and delivery by separating natural coitus between male and female from procreation. This miraculous advancement in reproductive medical technology has treated over 85% of the world's infertile couples. Surrogacy, a common variety of IVF, is another source of worry, particularly in developing nations, where womb rental has evolved as a new kind of exploitation of poor and uneducated women.

"Once issues of property and ownership and autonomy take centre stage, they displace competing cultural constructions of the body, other possible reactions to biotechnologies, and finally, the shaping of alternative ethical responses," Sharp observes. However, as Christine Sistare points out, the autonomy of choosing surrogacy is linked to reproductive rights. "A fundamental moral issue in the surrogacy debate is the

nature and extent of women's freedom: their freedom to control their bodies, their lives, their reproductive powers, and to determine the social use of those reproductive capacities," she says.

To maintain the purity of the lineage, several religions and personal laws prohibit third-party fertility interference. Adoption is prohibited in Islam, although a social institution called Kafalat, which deals with orphanage protection, is permitted. As a result, Muslims are more likely to use ARTs, yet severe religious prohibitions on third-party intervention in sexuality and fertility force them to seek cross-border reproductive tourism in countries with lax assisted fertility laws.

According to Islamic law, an IVF-born kid may be labelled as illegitimate, and the mother may be charged with Zina (adultery), creating suffering for both mother and child. With time, numerous religions that have adopted a harmonious structure have begun to accept a comprehensive reproductive care regime, with the stipulation that procreational sanctity and lineage purity be preserved. Providing right-based reproductive life to Lesbian-Gay-Bisexual-Transgender (LGBT) and poverty-prone infertile couples is a significant socio-legal challenge in many jurisdictions. ARTs have unquestionably strengthened procreational liberty as a matter of right during the last three decades, but they have also muddled the purity of lineage and socio-legal parenthood. Surrogacy, gamete donation, delayed pregnancies utilising cryopreserved embryos, single parenting; virgin mother (virgin birth), and live-in relationships are becoming increasingly acknowledged under the umbrella of human dignity, although this has resulted in masked parentage.

Medical advancements in human reproduction have far-reaching implications for preventing infertility around the world. Globalisation facilitated'reproductive tourism' in the twenty-first century, which encourages people to traverse borders and bodies. However, in the lack of a global legal framework for ARTs, reproductive tourism has seen a meteoric rise in cases of severe infertility, particularly in nations that impose strict religious-legal penalties for assisted reproduction. Unfortunately, the miracle of reproductive science has become a symbol of a thriving commercialised sector, with business centres dubbed fertility clinics, technocrats dubbed doctors, clients dubbed commissioning parents, and promoters dubbed intermediaries. Infertility clinics are accused of being exploitative money-making operations rather than serving the cause of mankind due to a lack of a proper legal framework. The commercial exploitation of reproductive science raises serious concerns about the remarkable development in the trend of renting wombs, which could lead to exploitation of underprivileged women, particularly in third-world nations. Progressive and career-oriented women are reportedly using medical science innovation to avoid the burden of pregnancy by renting a surrogate's womb to enjoy motherhood or opting for cryo-preservation of gametes and embryos to postpone conception. Another fancy ambition created by unlicensed IVF clinics is a designer baby. The Internet and social media sites offer enticing packages that commodify genetic content and the womb, attracting young generations to sell it under the guise of tourism. Trans-border reproductive tourism circumvents socio-legal norms, resulting in challenges in citizenship and immigration concerns.Ukraine, India, and the United States are growing as international surrogacy Meccas, with California in the United States becoming as a reproductive hotspot for IVF . India is one of a few countries that pays women to be surrogates, including Georgia, Thailand, Russia, Ukraine, and a few US states. The burgeoning reproduction industry must be examined via a bioethical lens in order to comprehend real-world situations by using theory and normative ideologies, particularly in order to comprehend competing stakeholder rights, such as a child's right to know his or her ancestry.

IV. SOCIAL DEVELOPMENT

"The physical and psychological burden the infertile couples are willing to go through, and the financial cost couples are willing to pay if they can afford it, attest to the high ranking of infertility as a perceived burden of disease." (Fathalla 2002, 5)

In order to prioritise health issues based on a quantitative assessment of the disability-adjusted life years (DALYs) lost due to disability, the World Bank Report Investing in Health published tables assessing the burden of disease in females by cause. Fathalla (Fathalla 2002) postulated that the rankings would alter if QALYs (quality-adjusted life years) were used in place of DALYs because infertility was not taken into account. According to him, if the ranking had been determined by how the handicap is seen rather than by production loss, infertility would have placed higher on the list. The false assumption that infertility has no severe and tangible impacts leads to the inability to prioritise ART and address infertility. (1995, Macklin) Because infertility does not always present as a sickness, it is not seen as a health hazard. It's important to remember that health isn't solely defined by the absence of disease.

Health also includes one's mental and social well-being. Infertility causes several hazards to one's social well-being, as we'll see below. Infertile couples endure a variety of effects as a result of their infertility, according to several research. (Gerrits 1999; Mulgaonkar 2001; Unisa 1999; Widge 2001) In this context, ART should be considered in order to meet demand, comprehend its accessibility, and assure parties' informed consent when deciding to undertake this operation under extreme social pressure.

Understanding gender concerns and expectations is essential to unravelling the social factors influencing the usage of ART. This is true because men's virility is seen as a sign of masculinity and women's duties as mothers are central to cultural expectations of marriage. Without a question, one of the most crucial elements of marriage is still having a "biological" child. The duo experience emotions of inadequacy as a result of society's expectations that parenting and reproduction are crucial to a woman's identity. The stigma associated with infertility in this setting puts a lot of pressure on the couple to conceive a biological child.Even if women's roles have expanded in today's society, reproduction remains a crucial determinant that influences thesocio-economic wellbeing' of most women in India (Das, Chen, and Krishnan, 1995)

According to a study conducted by Jindal and Gupta, the joint family arrangement exacerbates this pressure. (1989, Jindal and Gupta) They also discovered that social issues increased with the length of marriage and with the duration of infertility. However, these societal issues were negatively associated to the couple's education, the woman's economic independence, and the husband's salary.The social problems were caused by a desire to have a male kid, and they happened in couples who were experiencing primary infertility as well as secondary infertility after having a child. Infertile women reported having problems with their in-laws 34% of the time, and their husbands 16% of the time.

Infertility causes a stressful life and several invisible losses such as marital instability and a decrease in quality of life, according to a psychological study (Desai, Shrinivasan, and Hazra 1992) conducted to understand the emotions of infertile couples. The brunt of these losses is borne by women.Men blame their wives 40% of the time, while women blame themselves 36% of the time, even though they aren't the ones who are infertile. Several other research have confirmed that women are blamed for infertility regardless of their husband's role in it. (Mulgaonkar 2001; Devi YL 1980)

Infertility affected a woman's "social acceptability, her rightful function as a wife, her marital stability, security, bonding, and her role in the family and community," according to another study (Prakasamma 1999). Two-thirds of women in Unisa's (Unisa 1999) study on childlessness in Andhra Pradesh reported abuse from their husbands, with 13% believing that their childlessness played a role. Husbands threatened second marriages as a result of the couple's lack of children, in addition to physical abuse. However, as previously said, education did have an impact on women's lives. Women's conditions improved as it was realised that infertility was not primarily the fault of the woman and that it could be treated.

As a result, a public health effort to raise awareness about infertility is required. This is critical so that couples understand that infertility can be treated and that women are not necessarily to fault. They should also be aware of their choices if they want to start a family. This is critical not just to ensure that they are aware of ART, but also to introduce them to other options such as adoption or less invasive treatments such as intrauterine insemination. (2019, Hodson, Nathan, and Bewley)A regulatory framework for ART should therefore be implemented in tandem with a public health campaign on infertility to address the social repercussions of infertility.

V. HISTORICAL SET UP OF ASSISTED TECHNOLOGY

On August 6, 1986, India officially joined the brave new realm of assisted conception with the birth of Harsha, the first'scientifically documented' test-tube baby. The phrase "scientifically documented" has been used on purpose because it was frequently used in scientific circles to refute claims of a similar discovery made by a doctor in 1978, just a few months after Louise Brown, the first child ever to be born in a test tube, was born in the UK.Dr. Subhas Mukerji announced the birth of the second test-tube child in the world on October 3, 1978, in Calcutta. The media in India and, to a lesser extent, outside covered news extensively. However, Mukerji's assertion was disputed because he did not publish the majority of his research in recognised peer-reviewed publications. Ironically, Dr. TC Anand Kumar,is the person most directly linked with India's first "scientifically documented" IVF baby and he related the tale of Mukerji's test-tube child 19 years after the fact.According to Anand Kumar, "since the specifics of Mukerji's work were not then public," Harsha was referred to as India's first "scientifically recorded" test-tube baby.

In partnership with the King Edward Memorial Hospital, a tertiary care facility run by the Bombay Municipal Corporation, the National Institute for Research in Reproduction (NIRR) established an IVF programme in August 1984. Anand Kumar and his colleagues produced Harsha, the "first" test-tube baby in India, in Bombay in 1986 at the Institute for Research in Reproduction (now National Institute for Research in Reproduction or NIRR, which is an institute of ICMR). The Scientific Advisory Committee of the ICMR's Institute for Research in Reproduction and the Ethics Committee for Human Experimentation of the KEM Hospital gave their approval before this work could be carried out. Subsequently, two additional clinics in India reported IVF baby births that year.

The field of assisted reproductive technology (ART) has expanded dramatically since that time. There were no standardising norms available when India became one of the major centres of ART, leading in a slew of legal, ethical, and societal difficulties. The Official Guidelines for Accreditation, Supervision and Regulation of

ART Clinics in India were created by the ICMR in 2005 as the country's first-ever national surrogacy guidelines. The Law Commission of India took up the issue of the necessity for laws to control clinics that use assisted reproductive technology as well as the rights and obligations of those involved in a surrogacy on its own initiative. In its 228th Report, which was presented in 2009, the Commission emphasised that the legalisation of surrogacy and ART were extremely crucial.

When establishing ART centres, which should adhere to defined norms and guidelines, a rigorous accreditation method must be followed in order to guarantee the quality of care. The ICMR developed national guidelines for ART clinic accreditation, supervision, and regulation in 2005 to ensure that the best possible use of these more advanced technologies is made available to the appropriate people by qualified teams of professionals at reasonable health and financial costs in all public and private facilities in our nation. The ICMR shall maintain a nationwide registry pertaining to all centres that have received licencing authority accreditation, which registry shall include records of treatment cycles and results. The conduct of research using data collected as by-products of therapeutic action is a topic of equal importance. Researchers working in fundamental or molecular science can use the follicular fluid, oocytes, spare embryos, and semen samples among them.The ICPD (International Conference on Population and Development) Programme of Action includes prevention and appropriate treatment of infertility; as a result, the primary healthcare system should incorporate measures to reduce infertility. The majority of infertility issues, like genital TB and reproductive tract infections (RTI), are treatable and avoidable. However, about 8% of infertile couples require significant medical intervention requiring the use of cutting-edge ART techniques like IVF or ICSI.

VI. LEGAL DEVELOPMENT OF ART IN INDIA

The Pre-Natal Diagnostic Techniques Act-1994 was passed and updated as the Pre Conception- and Pre Natal-Diagnostic Techniques Act-2002 to prohibit the misuse of pre-natal diagnostic methods. The "Ethical Guidelines for Biomedical Research on Human Participants" (hereafter referred to as ethical guideline), released by ICMR in 2000, contained the first official mention of ARTs. The National Guidelines for Accreditation, Supervision and Regulation of the Assisted Reproduction Technology Clinics (hereinafter referred to as the ICMR guideline) were subsequently developed in 2005 by the Indian Council of Medical Research (ICMR) and the National Academy of Medical Sciences (NAMS) to regulate surrogacy.

Due to the lack of a legal obligation to abide by the rules and regulations contained in these guidelines, they were not fully followed, which led to the lack of any ART regulation. The Draft Assisted Reproductive Technology Bill & Rules 2008,which was released by the ICMR and the Ministry of Health and Family Welfare (MOHFW), was updated in 2010. This draft underwent numerous stage change and it was revised in the year 2014 and then in 2017.

Additionally, the Select Committee on the Surrogacy (Regulation) Bill, 2019, has advised that the ART Bill be introduced before the Surrogacy (Regulation) Bill, 2019, in order for the Surrogacy (Regulation) Bill, 2019, to appropriately handle all the highly technical and medical concerns.As a result, on September 14, 2020, the ART (Regulation) Bill, 2020 was introduced in the Lok Sabha. On October 3, 2020, the Chairman of the Rajya Sabha, in consultation with the Speaker of the Lok Sabha, referred the bill for review and a report to the Department-related Parliamentary Standing Committee on Health and Family Welfare.

The Lok Sabha passed the Assisted Reproductive Technology (Regulation) Bill, 2021 (ART Bill) on December 1 and the Rajya Sabha on December 8, respectively. The Bill aims to establish ethical practise in an area that has long been unregulated while also regulating ART clinics and banks. The Surrogacy (Regulation) Act, 2021, the first law in India to govern surrogacy services, was passed after much anticipation, yet cultural hostility to surrogacy persists, especially when the intended mother lacks a healthy egg and needs an egg donor for surrogacy.

VII. CONCLUSION

ART is one of the 20th century's most well-liked and successful medical advancements. Millions of infertile couples now have hope thanks to ART, but it has also brought up new moral, legal, and social problems that society needs to solve. Many countries have taken action to regulate certain parts of ART. The rules and laws that should govern ART reporting, social injustices that might arise from financial obstacles to ART, genetic testing, advanced laboratory techniques that have improved embryo and gamete survival when cryopreserved, and an individual's right to their genetic offspring in the context of gamete or embryo donation are some of the aspects of ART that will be hotly contested and debated in the future.The majority of ART-related ethical and legal questions, however, are still unresolved. Society must come to an agreement on how to fairly and sensibly finance ART in order to increase access to care. Future cultural and legal debates must also delve further into the myriad unresolved problems surrounding gamete and embryo donation. The art world is dynamic and always changing. The capabilities of ART in areas like preimplantation genetics are continually changing as a result of new technologies.Due to the ART's quick evolution, regulation frequently falls behind

and is unable to address all of the moral and legal questions that are continuously cropping up in the industry. Therefore, it is the obligation of medical professionals to keep an eye on these problems and make sure that ART technologies are supplied and provided in a way that combines patient care with social and moral responsibilities.

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